

Reverse Distribution

MANAGEMENT OF PHARMACEUTICAL WASTE WORKSHOP MAY 11, 2011

> Fredy Kadva Regional Sales Manager Guaranteed Returns Western Division 1-800-473-2138 x 155

Email: fkadva@guaranteedreturns.com

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What is a Reverse Distributor?

GENERAL OVERVIEW OF THE RETURNS INDUSTRY

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration
21 CFR Parts 1300, 1301, 1304, 1305, and 1307
[Docket No. DEA-108F] RIN 1117-AA19
Definition and Registration of Reverse Distributors
AGENCY: Drug Enforcement Administration (DEA), Justice.
ACTION: Final rule.

"A new type of business developed that collects controlled or noncontrolled substances from registrants and either returns them to the manufacturer or arranges for their disposal. The businesses performing this middleman service refer to themselves as ("reverse distributors" or "returns processors")"

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A reverse distributor provides services related to expired, recalled, damaged or overstocked pharmaceutical product returns for government, hospital, independent retail, chain-store and clinic pharmacies

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HISTORY

- ❖ Before the reverse distributors provided this service, unconventional methods were used to destroy product.
- ❖ Pharmacies returned product back to each individual manufacturer.
- ❖ Prior to 1986 no one knew what to do with their pharmaceutical returns.
- ❖ 1986 Guaranteed Returns opened its doors as the first reverse distributor in the industry.
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Who needs a reverse distributor?

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- **❖**Hospital (In patient or Out patient pharmacy)
- **❖**Retail pharmacy
- *DOD/VA
- *****Acute care facilities

► Some services depend on contract with GPO/buying group or facility

Overall: A pharmacy (carrying a current DEA license) that request expired or recalled pharmaceuticals to be returned back to the manufacturer for credit.

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Services Offered

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On-Site Service vs. Off-site service

❖Off-Site service: Customer mails in product. Also prepares items to ship back to reverse distributor

***On-Site service:** On-site service rep visits pharmacy and prepares items to send back to reverse distributor

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OFF-SITE SERVICE (mail in)

Pharmacy prepares and packages all products. Then completes a request for controls by providing a complete count of all controls to be sent back to reverse distributor. Once DEA paper work is received pharmacy sends all of the product back to reverse distributor.

ON-SITE SERVICE

Service representative prepares and packages all products, counts controls, fills out all DEA paper work for return on-site.

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What can I send back to my reverse distributor?

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- ❖ Any non-hazardous expired or recalled pharmaceuticals in original manufacturers packaging.
- **❖** Also includes schedule C2-C5 controlled product

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Where does my product go?

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- ❖ All product is sent back to the reverse distributor to process for credit.
- *****Once processed, all items are either sent directly to the manufacturer or disposed of according to all federal and local rules and regulations.

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Once all items are processed:

General reports are distributed to each customer to provide:

- >Anticipated dollar amount from manufacturer
- ➤ Returnable or non-returnable breakdown for each item. (Reports vary by company)
- >Proof of destruction.

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QUESTIONS???
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